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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,783	03/30/2004	Henrik S. Klint	10921/27	5211

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EXAMINER	
WOO, JULIAN W	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
12/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,783	KLINT ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 9, 12-16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Guglielmi et al. (5,122,136). Guglielmi et al. disclose, at least in figures 1-5 and in col. 5, line 57 to col. 8, line 15; a method for endovascular occlusion of a blood vessel area (64), aneurysm, or vessel lumen; where the method includes, inter alia, advancing a catheter (e.g., 44) in a blood vessel; mechanically pushing a wire body (e.g., 28 or 56) through the catheter, the wire body including a front end, a back end and a substantially straight section larger than a diameter of the blood vessel area; abutting a first wall portion of the blood vessel area, the wire body being substantially in an unloaded condition within the catheter; continuing to mechanically push the wire body out of a distal opening of the catheter, thereby by curving the section of the wire body toward a second wall portion of the blood vessel area, and frictionally locking the section to the first and second wall portions, where the length of the section of the wire body is at least 20 mm, or at least 90 mm., where the wire body is made of thread extending helically around a center line of the wire body and absent of

occlusion hairs, and where mechanically pushing the wire body comprises pushing on a guidewire (10).

3. Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritchart et al. (4,994,069). Ritchart et al. disclose, at least in figures 1 and 7-9C and in col. 6, line 39 to col. 7, line 33; a method for endovascular occlusion of a blood vessel area (70); where the method includes, inter alia, advancing a catheter (e.g., 12) in a blood vessel; mechanically pushing a wire body (e.g., 14) through the catheter, the wire body including a front end, a back end and a substantially straight section larger than a diameter of the blood vessel area; abutting a first wall portion of the blood vessel area, the wire body being substantially in an unloaded condition within the catheter; continuing to mechanically push the wire body out of a distal opening of the catheter, thereby by curving the section of the wire body toward a second wall portion of the blood vessel area, and frictionally locking the section to the first and second wall portions, where mechanically pushing the wire body comprises pushing on a stylet (16).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 6-8, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi et al. (5,122,136). Guglielmi et al. disclose the invention substantially as claimed. Guglielmi et al. disclose, in col. 6, lines 28-32; a method for endovascular occlusion, where the front end of a body is formed as a spiral with a decreasing helix diameter in the direction of the front (i.e., "conical" shape), and where a complexly curved shape of the wire body is formed within a vessel without a change in temperature of the wire body; but they do not specifically disclose retracting the catheter between the abutting and continuing steps, that the wire body has a spring constant as claimed, and that the wire body is dimensioned as claimed. Nevertheless, Guglielmi et al. also disclose, at least in col. 5, lines 41-45 and col. 6, lines 48-60, that a long wire body may be applied at various vascular sites of different shapes and may be moved to at least expose a portion of the guidewire to blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to retract the catheter between the abutting and continuing steps. Such a step would allow a surgeon to reposition the catheter, so that the catheter can deliver

a wire body and fill a vascular site, so that the catheter distal end does not interfere with the space-filling conformation of the wire body within the blood vessel area, and so that a portion of the guidewire may be exposed to blood for detachment of the wire body from the guidewire..

It also would be a matter of obvious design choice to size the section and the rest of the wire body as claimed, since such modifications would have involved mere changes in the size of a component. A change in size is generally recognized as being within the skill of ordinary skill in the art. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the wire body, so that it has a spring constant as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (e.g., of a spring constant) involves only routine skill in the art.

6. Claims 3, 4, 10, 11, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi et al. (5,122,136) in view of Kupiecki et al. (5,669,931). Guglielmi et al. disclose the invention substantiallly as claimed. However, Guglielmi et al. do not disclose that the front end and/or the back end of the wire body are each curved in an unloaded condition at least 120 deg., that the back end of the wire body is curved in the unloaded condition between 140 deg. and 340 deg., or that the front and the back ends are curved, and that the wire body is sized as claimed. Kupiecki et al. teach, at least in col. 4, line 62 to col. 5, line 5, that a wire body may have curves (i.e., helices) at the front end,

along the entire length of the body, or spaced from the front end. Thus, it would have been a matter of obvious design choice, in view of Kupiecki et al., to curve the front and back ends of the wire body of Guglielmi et al. (at least 120 deg. or between 140 deg and 340) in an unloaded condition. Such modifications (i.e., helices) would enhance the occlusion of a vascular site to a desired degree with additional masses of wire body material concentrated at the ends of the wire body upon unloading of the wire body. Moreover, it also would be a matter of obvious design choice to size the section and the rest of the wire body as claimed, since such modifications would have involved mere changes in the size of a component. A change in size is generally recognized as being within the skill of ordinary skill in the art.

Response to Amendment

7. Applicant's arguments filed on September 11, 2007 have been fully considered but are moot in view of the new grounds of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho, can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

December 2, 2007